

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

SOUTHEASTERN PENNSYLVANIA
TRANSPORTATION AUTHORITY, JANE
DOE, and JOHN DOE, individually and on
behalf of all others similarly situated,

Plaintiffs,

v.

GILEAD SCIENCES, INC.,

Defendant.

Case No. 2:14-cv-06978-SD

The Honorable Stewart R. Dalzell

**REPLY MEMORANDUM IN SUPPORT OF DEFENDANT'S 12(b)(6) MOTION
TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT**

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INTRODUCTION

Plaintiffs argue that, “[i]f nothing else, this case . . . demonstrate[s] that the American health care system is in desperate need of a fix.” Plaintiffs’ Memorandum of Law in Opposition to Defendant’s Motion to Dismiss, ECF. No 18 (“Opp.”) at 3. If Plaintiffs want to lobby for health care reform, they are entitled to write an editorial or send a letter to their Congressman. They are not entitled to bring a baseless lawsuit.

In their fifty-one-page brief, Plaintiffs discuss policy issues and make irrelevant *ad hominem* assertions.¹ They do not state a claim. Plaintiffs’ Affordable Care Act (“ACA”) claim fails because they do not allege discrimination *on the basis of* membership in a protected class, and their state claims are preempted by federal patent law and are otherwise invalid. Because further amendment cannot cure these flaws, the complaint should be dismissed with prejudice.

ARGUMENT

I. Plaintiffs’ ACA Claim Fails For Lack of Discrimination

Plaintiffs urge this Court to use the ACA to weigh in on a “heated public debate” regarding pharmaceutical pricing. Opp. at 1. But Plaintiffs cite *nothing* in the ACA directing courts to evaluate whether companies’ prices are “reasonable,” Opp. at 31, and indeed such judicial price regulation would be a radical departure from existing law.²

Like other antidiscrimination statutes, the ACA prohibits discrimination “on the basis of” a person’s protected status. 42 U.S.C. § 18116. This requires showing that the plaintiff was

¹ Plaintiffs also include, without explanation or motion, 40 pages of articles, shareholder proxy materials, and an affidavit. These are not properly presented and, in any event, do not save Plaintiffs’ claims. *Frederico v. Home Depot*, 507 F.3d 188, 202 (3d Cir. 2007) (“It is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss.”); *Mast v. Lafayette Coll.*, 2015 WL 409774, at *3 (E.D. Pa. Jan. 30, 2015) (dismissing where new allegations did not save meritless claim).

² Recognizing this, Plaintiffs argue that they “do not seek to have this Court set prices,” but in the next breath say they would like to present “pricing data” so that the Court can “establish” “fair prices.” Opp. at 30. The Supreme Court has repeatedly held that statutes should not be construed to effect radical changes in the law *sub silentio*. See, e.g., *United States v. Bestfoods*, 524 U.S. 51, 62 (1998).

treated less favorably than unprotected people *because of* the plaintiff's protected status. *See, e.g., Jackson v. Birmingham Bd. of Educ.*, 544 U.S. 167, 174 (2005) (discrimination means adverse treatment "on the basis of" a person's protected status); *CG v. Pa. Dep't of Educ.*, 734 F.3d 229, 236 (3d Cir. 2013) ("Plaintiffs must prove that they were *treated differently based on the protected characteristic*"). Indeed, Plaintiffs concede as much. *See* Opp. at 26 (noting precedent turning on "mistreatment of the plaintiff on the basis of a protected class").

Here, Plaintiffs allege that the price of (and thus access to) Gilead's HCV treatments varies based on HCV patients' ability to pay or various corollaries thereto, including whether they have insurance, whether their plan has negotiated a discount, and in which country they reside. Opp. at 18-19. Plaintiffs then assert in conclusory fashion that they have been treated adversely "on account of their protected HCV status." Opp. at 26. This conclusion does not follow, and indeed is belied by Plaintiffs' own allegations that the *beneficiaries* of the alleged discounts are also HCV sufferers. In short, the alleged price difference among HCV patients is based only on *unprotected* factors, in particular, ability to pay. As in *Williams v. 5300 Columbia Pike*, price is neutral to protected status. 103 F.3d 122, 1996 WL 690064 (4th Cir. 1996) (unpublished). Plaintiffs try to distinguish *Williams* as a Fair Housing Act ("FHA") case, but the FHA, just like § 1557 of the ACA, applies only to discrimination "on the basis of" a protected category, and the protected categories do not include ability to pay. 42 U.S.C. § 3604(d).

Plaintiffs' own cases further confirm the need to allege discrimination *based on* protected status.³ In *Rumble v. Fairview Health Servs.*, 2015 WL 1197415 (D. Minn. Mar. 16, 2015), for example, a hospital refused to treat a transgender man "*because of [his] gender identity*." *Id.* at

³ Plaintiffs use the catch phrase "deliberate indifference," but this is not an alternative way to establish discrimination, but rather a theory for determining who can be held liable for intentional discrimination committed by others, which is not Plaintiffs' theory here. *See Gebser v. Lago Vista Indep. Sch. Dist.*, 524 U.S. 274, 290 (1998).

*18. Similarly, in *Bragdon v. Abbott*, the plaintiff was denied dental services *because she had HIV*. 524 U.S. 624, 628-29 (1998). In Plaintiffs’ other cases, an individual who was found to be disabled as a result of HCV—not a purported class of all people with HCV—suffered an adverse employment action *because of that disability*.⁴

Nor does Plaintiffs’ citation to a footnote in *East v. Blue Cross and Blue Shield of La.*, 2014 U.S. Dist. LEXIS 23916, at *4 n. 1 (M.D. La. Feb. 24, 2014), save their ACA claim. The plaintiff in *East* challenged the defendant insurance plan’s decision to stop accepting third-party payment of premiums. *Id.* at *1-2. He did not demand that the defendant change its pricing: He asked only that the defendant continue accepting payment regardless of source. *Id.* at *4-5. And, unlike Plaintiffs here, East alleged the defendant plan was discriminating *on the basis of* his disability by refusing payments from a fund that assisted disabled people, in the apparent hope of driving (costly) disabled people out of the plan. The footnote to the brief decision in *East* granting a Temporary Restraining Order does not support Plaintiffs’ claim.⁵

Finally, Plaintiffs mistakenly argue that Gilead’s pricing violates § 1557 because the pricing has a “disparate impact” on a protected class. Opp. at 31; *but see* Opp. at 32.⁶ But § 1557 does not prohibit “disparate impact” discrimination. The Supreme Court has explained

⁴ *Powell v. City of Pittsfield*, 221 F. Supp. 2d 119, 149-150 (D. Mass. 2002) (plaintiff not reinstated because of disability); *Quick*, 43 F. Supp. 2d 1357, 1361 (S.D. Fla. 1999) (plaintiff terminated because of disability); *White*, 2000 WL 1664162, at *1 (N.D. Tex. Nov. 2, 2000) (same); *Rolf*, 1999 WL 1095768, at *1 (E.D. Mo. Nov. 4, 1999) (same). Plaintiffs imply that HCV is a disability “per se” because HCV patients refrain from the major life activity of reproduction to avoid transmitting the disease. Opp. at 20. But Plaintiffs concede that “50% to 75% of those who have [HCV] do not know they are infected.” AC ¶ 24. A majority of Plaintiffs’ proposed class of “Americans living with HCV,” AC ¶¶ 117-18, are thus not voluntarily limiting major life activities and are not disabled under the law.

⁵ In addition, a different provision of the ACA than the one relied upon here, § 1311, subjects insurance plans to specialized anti-discrimination language.

⁶ Confusingly, Plaintiffs slur together different standards and at times refer to claims under the Civil Rights Act and the Rehabilitation Act. Opp. at 16-17, 23, 31-32. As the counts in the Amended Complaint make clear, Plaintiffs are not bringing a claim under either of these statutes. Section 1557 of the ACA incorporates *only* the protected grounds these earlier statutes enumerate, not the entire text of the other statutes. *Rumble*, 2015 WL 1197415, at *11-12.

unequivocally that language identical to that used in §1557 “prohibits only intentional discrimination.”⁷ *Alexander v. Sandoval*, 532 U.S. 275, 280 (2001). Congress’s re-use of wording from a prior statute “carries with it the previous judicial interpretations of the wording.” *Carolene Prods. Co. v. United States*, 323 U.S. 18, 26 (1944).⁸ By re-using the language of Title VI, Congress manifested a clear intent that § 1557 of the ACA also reach only intentional discrimination. Other language in the ACA confirms this point: § 1311 of the ACA applies a heightened standard to insurance plans, barring insurers from using practices “that have *the effect* of discouraging the enrollment in such plan by individuals with significant health needs.” 42 U.S.C. §18031(c)(1)(A) (emphasis added). This “effects” language, which is limited to insurers, confirms that, where Congress intended to reach disparate *effects*, it said so.⁹

Moreover, Plaintiffs have not alleged facts showing that Gilead’s conduct adversely affected a protected class as compared to “similarly situated” individuals “who are not members of a protected class.” Opp. at 32 (quotation omitted). Plaintiffs do not allege that Gilead’s pricing adversely affected those who are disabled as compared to those who are not. Indeed, they allege that *everyone* who uses Gilead’s products is disabled. Opp. at 19. Nor do Plaintiffs allege that Gilead’s conduct adversely affected racial minorities compared to non-minorities.

⁷ Title VI and the ACA both state that an individual shall not “on the ground” of membership in a protected category “be excluded from participation in, be denied the benefits of, or be subjected to discrimination under” any covered program. ACA § 1557, 42 U.S.C. § 18116; Title VI of the Civil Rights Act of 1964, 42 U.S.C. § 2000d.

⁸ Section 504 of the Rehabilitation Act has the same text but has been held by lower courts to permit disparate impact claims based on the legislative history of that statute. *Alexander v. Choate*, 469 U.S. 287, 293 (1985) (explicitly not deciding issue). But Section 504, unlike the ACA, was enacted long before the Supreme Court’s definitive interpretation of the text at issue in *Sandoval*. 29 U.S.C. § 794 (1973).

⁹ *Keene Corp. v. United States*, 508 U.S. 200, 208 (1993) (where language appears in one part of statute but not another, omission presumed intentional). Congress also used different language to reach disparate impact in other statutes. Title VII, for example, prohibits acts that “*tend to deprive* any individual of employment opportunities *or otherwise adversely affect*” him because of his protected status. 42 U.S.C. § 2000e-2(a)(2) (emphasis added); *Griggs v. Duke Power Co.*, 401 U.S. 424, 432 (1971) (“Congress directed the thrust of [Title VII] to the consequences of employment practices . . .”).

Plaintiffs say *HCV* has a disproportionate effect on African Americans. But Plaintiffs are not suing HCV. Plaintiffs do not allege that, of those people with HCV, minorities are systematically charged a higher price than non-minorities. On the contrary, Plaintiffs allege that a disproportionate number of African Americans are in prison, AC ¶ 133, and that the Bureau of Prisons receives especially *low* pricing. *Id.* at ¶ 7. And, in any event, Plaintiffs are not bringing claims on behalf of African Americans – they do not allege a class of African Americans, and the named plaintiffs do not allege they are African American. AC ¶¶ 21, 22, 117. Gilead’s pricing also did not proximately cause any injury. *See Serodio*, 2013 WL 5503528 at *5; AC ¶¶ 21-22.

II. Plaintiffs’ State Law Claims Fail Because They Are Preempted and Lack Merit

A. Plaintiffs’ State Law Claims Are Preempted By Federal Patent Law

Plaintiffs’ state law claims are preempted. Br. at 12-14 (citing *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007)). *Biotechnology* is directly on point: It held that state law is preempted from regulating prices for patented drugs. *Biotechnology* is also controlling. “Federal Circuit law governs whether federal patent law preempts a state law claim.” *Ultra-Precision Mfg., Ltd. v. Ford Motor Co.*, 411 F.3d 1369, 1376 (Fed. Cir. 2005); accord, e.g., *IMCS, Inc. v. D.P. Tech. Corp.*, 264 F. Supp. 2d 193, 196 n. 5 (E.D. Pa. 2003). Plaintiffs do not even attempt to distinguish *Biotechnology*. Rather, they cite a dissent from the denial of rehearing in the case, disagreeing with the holding. Opp. at 37. Plaintiffs cannot avoid *Biotechnology* by citing a dissent. Nor can they go beyond it, as they attempt to by having a court, rather than the market or even a state legislature, “establish” drug prices. Opp. at 30.¹⁰

Nor can Plaintiffs avoid preemption by suggesting that Gilead’s patents “may not” be valid. Opp. at 10. An issued U.S. patent is presumed valid. 35 U.S.C. § 282(a). Plaintiffs have

¹⁰ Plaintiffs’ other citations are irrelevant. *See Leatherman Tool Grp. v. Cooper Indus.*, 131 F.3d 1011, 1014-15 (Fed. Cir. 1997) (no jurisdiction over appeal of non-patent claim); *TransCore v. Elec. Transaction Corp.*, 563 F.3d 1271, 1275 (Fed. Cir. 2009) (patentee can only convey a freedom from suit).

not alleged invalidity of *any* patent protecting Sovaldi or Harvoni, much less *all* patents covering those treatments. Plaintiffs cite a decision by the Indian Patent Office rejecting a Gilead patent application but, as Plaintiffs acknowledge, that decision has already been overturned, Opp. at 10 n. 3, and a decision applying foreign patent law is irrelevant. *Medtronic, Inc. v. Daig Corp.*, 789 F.2d 903, 907 (Fed. Cir. 1986) (rejecting reliance on German patent proceeding); *Heidelberger Druckmaschinen AG v. Hantscho, Inc.*, 21 F.3d 1068, 1072 n. 2 (Fed. Cir. 1994) (“[T]he theories and laws of patentability vary from country to country, as do examination practices.”). Plaintiffs also allege infringement suits against Gilead, Opp. at 10, but these have no bearing on the validity of Gilead’s own patents.

Finally, Plaintiffs say patent law does not authorize “exorbitant prices.” Opp. at 10. But “[t]he owner of a patented article can, of course, charge such price as he [may] choose.” *United States v. Gen. Elec. Co.*, 272 U.S. 476, 491 (1926); *see Schor v. Abbott Labs.*, 457 F.3d 608, 610 (7th Cir. 2006) (“a patent holder is entitled to charge whatever the traffic will bear”); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006) (“[T]he patent system provides incentive to the innovative drug companies to continue costly development efforts.”). Plaintiffs’ state law claims regarding the pricing of patented products are preempted.

B. Each of Plaintiffs’ State Law Claims Fails Independently

1. Plaintiffs’ California UCL Claim Fails

In addition to being preempted, Plaintiffs’ UCL claim fails for three independent reasons. *First*, it is well established that the UCL does not authorize courts to invade the province of the legislature by wading into “complex policy determinations” that courts are “ill-equipped” to handle. *Winans v. Emeritus Corp.*, 2014 WL 970177, at *7 (N.D. Cal. Mar. 5, 2014). Yet Plaintiffs would have this Court do exactly that. *See, e.g.*, Opp. at 1 (asking Court to address a “significant public policy issue” regarding drug pricing and access); *id.* at 12 (citing “compelling

and confounding” policy issues). In *Boris v. Wal-Mart Stores, Inc.*, 35 F. Supp. 3d 1163, 1171-72 (C.D. Cal. 2014), the court specifically refused an invitation to regulate drug prices under the UCL because “price regulation is a political question beyond the judiciary’s authority.” Plaintiffs’ only responses are that the conduct in *Boris* that was held not to violate the UCL: (1) involved allegations related to deception and product efficacy, as well as price, Opp. at 42-43; and (2) raised only “pedestrian” facts whereas this case raises “significant public policy issues.” *Id.* These factors simply confirm that application of the UCL would be even less proper here.¹¹

Second, Plaintiffs’ UCL claim fails under any test. As a threshold matter, the “tethering test” in *Cel-Tech Commc’ns, Inc. v. Los Angeles Cellular Tel. Co.*, 973 P.2d 527, 541 (Cal. 1999), requiring that a UCL violation be tethered to some other violation, is the correct standard here. *Cel-Tech* rightly criticized the balancing test Plaintiffs invoke as “too amorphous” because it “provide[s] too little guidance to courts and businesses.” *Id.* at 543. Indeed, in *Boris*, the UCL case most analogous to this one, the court employed the tethering test, “because it maintains the UCL’s purpose of deterring and remedying unfair business conduct yet avoids exposing business to arbitrary or unpredictable liability.” 35 F. Supp. 3d at 1171.¹² But Plaintiffs’ UCL claim also fails even under the outdated balancing test they prefer. Plaintiffs do not cite a single case holding that a price alone violates the UCL under a balancing test. And, in fact, a California appellate court looked at this precise question and “uncovered no UCL cases in which a court has found a charge to be ‘excessive’ in the absence of deceptive or misleading information about it.” *Kent v. Avis LLC*, 2012 WL 831561, at *9 (Cal. Ct. App. Mar. 13, 2012) (unpublished); *cf.*

¹¹ Plaintiffs argue that because the relief they seek includes price “transparency,” the Court need not address complex policy issues. Opp. 44-45. But Plaintiffs also ask the Court to “establish” a “fair” price. Opp. at 30. And Plaintiffs repeatedly concede they are asking the Court to intervene in the policy arena. *See, e.g.*, Opp. at 1 (asking Court to enter a “heated public debate over a significant public policy issue”).

¹² Plaintiffs say their claim survives under the tethering test due to a purported violation of the ACA, Opp. at 43, but this fails along with Plaintiffs’ deficient ACA claim.

Fabozzi v. StubHub, Inc., 2012 WL 506330, at *7 (N.D. Cal. Feb. 15, 2012) (“So long as purchasers . . . are getting exactly what they paid for . . . at a price they are willing to pay, it is hard to understand how such a transaction could be deemed unfair.”).

Third, Plaintiffs lack standing under the UCL because they did not suffer an economic injury. *Kwikset Corp. v. Super. Ct.*, 246 P.3d 877, 884-85 (Cal. 2011). The Does lack UCL standing because they did not buy Gilead’s products. Br. at 18. Plaintiffs do not dispute, and thus concede, this lack of standing. Opp. at 45-46; *Hanoverian, Inc. v. Pa. Dep’t of Env’tl. Prot.*, 2008 WL 906545, at *16 (M.D. Pa. Mar. 31, 2008) (if plaintiff’s response brief “fails to address certain arguments made by the defendant, the court may treat those arguments as conceded”). And SEPTA suffered no economic injury because it received the benefit of its bargain. Br. at 18-19. Plaintiffs argue that SEPTA “overpaid,” and cite one case, *Clayworth v. Pfizer*, 233 P.3d 1066, 1086-87 (Cal. 2010). In that case, indirect purchasers who overpaid *due to an alleged price fixing conspiracy* were found to have standing. See Opp. 45-46. *Clayworth* is inapplicable here, where Gilead unilaterally set a price and Plaintiffs allege no deception or conspiracy. SEPTA’s claim is foreclosed because it received the benefit of its bargain.¹³

2. Plaintiffs’ Unjust Enrichment Claim Fails

Although the complaint does not say it, Plaintiffs now argue they are bringing their unjust enrichment claim under California law or, in the alternative, under the law of Pennsylvania (SEPTA and Jane Doe) or perhaps Arizona (John Doe). Plaintiffs cannot amend their complaint through their brief, *see supra* n. 1, and, in any event, the claim fails in any of these states.

California has no cause of action for unjust enrichment. *United Food v. Teikoku, Inc.*, 2014 WL 6465235, at *29 (N.D. Cal. Nov. 17, 2014) (“unjust enrichment is not an independent

¹³ Plaintiffs also cite *Clayworth* for the irrelevant point that a buyer does not lose standing by mitigating its loss. SEPTA has no standing because it got the benefit of its bargain, and thus suffered no loss at all.

cause of action.”). Plaintiffs argue to the contrary, Opp. at 46-48, but, as a federal court recently noted, “[n]otwithstanding earlier cases suggesting the existence of a separate, stand-alone cause of action for unjust enrichment, the California Court of Appeals has recently clarified that ‘unjust enrichment is not a cause of action, just a restitution claim.’” *Williamson v. Reinalt-Thomas Corp.*, 2012 WL 1438812, at *5 (N.D. Cal. Apr. 25, 2012) (citation omitted).

Plaintiffs’ unjust enrichment claim also fails because none of the named Plaintiffs may bring such a claim. Plaintiffs concede that the Does did not purchase Gilead’s products. AC ¶¶ 21-22. The Does thus have not conferred a benefit on Gilead as required to bring an unjust enrichment claim in any state. *See In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46, 58 (D.N.J. 2009) (summarizing universal principles of unjust enrichment). As for SEPTA, its purported California / Pennsylvania claim fails because it received what it paid for. Both California (to the extent it considers unjust enrichment at all) and Pennsylvania bar a purchaser from claiming unjust enrichment because it thinks it paid too much. *Peterson*, 80 Cal. Rptr. 3d at 323 (Ct. App. 2008); *Johnson*, 365 F. App’x at 832 (9th Cir. 2010); *Coregis Ins. Co. v. Kafrisen*, 140 F. Supp. 2d 461, 463 (E.D. Pa. 2001) (“[I]t is elementary that one who voluntarily pays money with full knowledge of the facts, without any fraud having been practiced upon him, cannot recover it back.”). SEPTA alleges no fraud or lack of knowledge and cannot pursue an unjust enrichment claim. *Abrevaya v. VW Credit Leasing*, 2009 WL 8466868, at *1 (E.D. Pa. July 22, 2009) (Dalzell, J.) (dismissing claim in light of voluntary payment); *Corporate Aviation v. Multi-Serv. Aviation*, 2005 WL 1693931, at *5-6 (E.D. Pa. July 19, 2005) (same).

3. Plaintiffs’ Contract Claim Fails

Plaintiffs assert that, by charging agreed-upon prices that it “extracted,” Gilead breached a duty of good faith as to contracts it entered with unnamed parties on unspecified terms. Opp. at 49. But compliance with pricing terms is not bad faith. *See Br.* at 20-22. Plaintiffs cite only two

cases in response. In both, banks took actions on which the contracts at issue were *silent* (posting transactions in non-chronological order so as to maximize overdraft fees), and the plaintiffs were not seeking “to vary express terms of the contract.” *In re Checking Account Overdraft*, 694 F. Supp. 2d 1302, 1308-09 (S.D. Fla. 2010); *Hughes*, 856 F. Supp. 2d 673, 676 (D.N.J. 2012). Here, Plaintiffs *are* attacking express terms of the contracts. Opp. at 49 (attacking as “excessive” prices Gilead “extracted”). This claim also fails because Plaintiffs allege no support for their claim that they are intended third party beneficiaries, and fail to address the case law holding that a sales contract is not intended to benefit subsequent customers following resale. Br. 20-21. Instead, Plaintiffs argue it is *Gilead’s* burden to advance its own factual allegations. Opp. at 51. This is not the law: To state a claim, a plaintiff must provide factual heft in support of its claims. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007).

III. The Complaint Should Be Dismissed With Prejudice As Amendment Is Futile

The law does not support Plaintiffs’ demand that the Court set prices for Gilead’s patented products, and no amendment can change that reality. Because amendment would be futile, and because Plaintiffs have identified no additional facts they could allege to support their claims, the Amended Complaint should be dismissed with prejudice. *Unger v. Nat’l Residents Matching*, 928 F.2d 1392, 1401 (3d Cir. 1991) (affirming dismissal with prejudice of claim that was “not cognizable under the law”); *U.S. ex rel. Zizic v. Q2Administrators, LLC*, 728 F.3d 228, 243 (3d Cir. 2013) (“bare request” to amend “in an opposition to a motion to dismiss—without any indication of the particular grounds on which amendment is sought” is properly denied).

CONCLUSION

For the foregoing reasons, and for the reasons stated in its opening brief, Gilead respectfully requests that the Court grant its motion and dismiss the Amended Complaint with prejudice.

By: /s/ George S. Cary

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March 30, 2015

CERTIFICATE OF SERVICE

I, George S. Cary, do hereby certify that on this date, I caused a true and correct copy of the foregoing document to be served upon the following counsel via electronic means:

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